Before the FEDERAL COMMUNICATIONS COMMISSION Washington, DC

| In the Matter of |) | |
|---|---|---------------------|
| |) | |
| Sensible Medical Innovations Request for |) | ET Docket No. 18-39 |
| Waiver of Part 15 of the Commission's Rules |) | |
| Applicable to Ultra-Wideband Devices |) | |

REPLY COMMENTS OF SENSIBLE MEDICAL INNOVATIONS

Sensible Medical Innovations Ltd. ("Sensible"), through its counsel, submits these reply comments in response to the public notice released by the Commission's Office of Engineering and Technology on February 8, 2018. The public notice seeks comment on Sensible's request for a limited waiver of the Commission's Part 15 rules governing ultra-wideband ("UWB") medical imaging devices in order to market a medical monitoring device that uses dielectric sensing to provide non-invasive monitoring to patients suffering from congestive heart failure (the "ReDS System"). The National Public Safety Telecommunications Council supported the request, noting the benefits the ReDS System would provide to patients and emergency medical service personnel and low risk of interference to other communications. Sensible now responds in turn to comments filed by the GPS Innovation Alliance ("GPSIA"), Iridium Communications ("Iridium"), and the National Radio Astronomy Observatory ("NRAO"), which seek additional information about the ReDS System.

¹ Office of Engineering and Technology Seeks Comment on Sensible Medical Innovations Ltd's Request for Waiver of Part 15 Ultra-Wideband Rules for Medical Imaging System, Public Notice, DA 18-131 (OET, rel. Feb. 9, 2018).

² Sensible, Request for Waiver, ET Docket No. 18-39 (filed Jan. 16, 2018) ("Waiver Request"). ³ See The National Public Safety Telecommunications Council, Comments, ET Docket No. 18-39, at 5-7 (filed Mar. 12, 2018).

I. **Reply to GPSIA's Comments**

GPSIA suggests that additional technical information is necessary to ensure that GPS is protected from interference.⁴ For example, GPSIA claims that Sensible did not identify the 16 frequencies that the ReDS System's electromagnetic signal sweeps through and that, without a list of these frequencies, neither it nor the Commission can determine whether a ReDS device would cause harmful interference to GPS users in its vicinity.⁵

ReDS devices currently emit in 16 discrete frequencies in the 1005-1709 MHz band. A table of these frequencies follows:

Table 1: ReDS Frequencies

| # | Frequency | | |
|----|-----------|--|--|
| | [MHz] | | |
| 1 | 1005.0625 | | |
| 2 | 1083.0625 | | |
| 3 | 1164.0625 | | |
| 4 | 1243.0625 | | |
| 5 | 1257.0625 | | |
| 6 | 1303.0625 | | |
| 7 | 1347.0625 | | |
| 8 | 1417.0625 | | |
| 9 | 1427.0625 | | |
| 10 | 1492.0625 | | |
| 11 | 1517.0625 | | |
| 12 | 1611.0625 | | |
| 13 | 1629.0625 | | |
| 14 | 1655.0625 | | |
| 15 | 1657.0625 | | |
| 16 | 1709.0625 | | |
| | | | |

Specifically, 1164.0625 MHz falls within (by 0.0625 MHz) the Safety-of-Life ("SoL") RNSS L5 downlink band, and 1243.0625 MHz and 1257.0625 MHz frequencies fall within the L2 RNSS

 $^{^4}$ See GPSIA, Comments, ET Docket No. 18-39 (filed Mar. 12, 2018). 5 Id. at 5.

downlink band. Sensible tests have shown that peak power in these frequencies is below 47 $dB\mu V/m$ at a distance of three meters.

Moreover, the ReDS System is used indoors, while satellite navigation systems primarily operate outdoors. ReDS devices also use low power transmissions, and energy is coupled into a patient's body, resulting in extremely low power leakage – at least 27 dB below the limits that are applicable to unintentional consumer appliances. Sensible's link budget calculation, detailed below, indicates that signals from the ReDS System are below the GPS noise level under worst case conditions at a distance of 50 meters or more.

The GPS interference calculation below assumes worst case conditions, considering maximal ReDS peak and average power of 47 dB μ V/m and 26 dB μ V/m at three meters, respectively. The ReDS device is operated indoors with a low duty cycle and low device density and with a bandwidth of less than 0.25 kHz (pulse of about 4.5 ms). It should be noted that the GPS receiver would likely further filter the ReDS device signal because 1164.0625 MHz is on the very edge of the L5 band and outside the modulation main lobe. The calculation below refers to the 1164.0625 MHz frequency, and similar results are expected at 1243.0625 and 1257.0625 MHz.

Table 1: ReDS Interference to RNSS – Link Calculations

| GPS Parameters | | |
|---------------------|---------|--------|
| GPS Effective Noise | | |
| Floor | -172.00 | dBm/Hz |
| ReDS BW | 0.25 | kHz |
| Spread Code Rate | 10.23 | MHz |
| Spread interferer | | |
| suppression Gain | 46.12 | dB |

⁶ See 47 C.F.R. § 15.109.

⁷ Recent testing measured pulse lengths of up to 4.3 ms, and 4.5 ms may be considered a maximum.

| Frequency | 1164.063 | [MHz] | |
|-----------------------|----------|--------------|--|
| Peak Power | 47.0 | [dBµv/m] @3m | |
| Peak Power [EIRP] | -48.2 | [dBm] | |
| Distance | 50.0 | [meter] | |
| Wall Attenuation | 15.0 | [dB] | |
| Free Space Loss | 67.7 | [dB] | |
| Total Attenuation | 128.9 | [dB] | |
| Equivalent Received | -177.1 | | |
| Power | | [dBm] | |
| Interference to Noise | -5.1 | | |
| Peak Power | | [dB] | |
| Interference to Noise | -26 | | |
| Average Power | | [dB] | |

As the table shows, in the very worst case peak power from a ReDS device will be 5.1 dB below a GPS receiver's noise floor at a distance of 50 meters, and average power will be 26 dB below. In addition, the very low duty cycle of 90 seconds per day per patient and the low density of ReDS devices means that the likelihood of interference events to GPS receivers is extremely low.

II. **Reply to Iridium's Comments**

Iridium also seeks additional technical information about the ReDS System ⁸ and suggests that, if the Commission grants Sensible's request, it should impose conditions to protect Iridium's operations in the 1617.775-1626.5 MHz band.⁹

Sensible provided much of the information requested by Iridium in our above reply to GPSIA. 10 In addition, Sensible observes that the frequencies used by ReDS devices do not fall within the Iridium frequency band and that, even if they did, ReDS devices would pose no risk of harmful interference to Iridium operations. ReDS devices operate indoors, have a negative interference to noise ratio, have a low duty cycle of 90 seconds once per day per patient to obtain

⁸ See Iridium, Comments, ET Docket No. 18-39 (filed Mar. 12, 2018). ⁹ See id. at 5-6.

¹⁰ See supra Section I.

a lung fluid content measurement, and have a low device density. Further, Iridium devices typically operate outdoors and in remote areas in which terrestrial wireless communication services are not available. To interfere with an Iridium receiver, the interference power density from a ReDS device would need to be higher than the maximum allowed narrowband interference of -134 dBm.¹¹ The ReDS System would not reach this level, as shown in the table below.

Table 3: Iridium Interference Link Budget

| | _ | |
|----------------------------------|--------------------|--------------|
| Maximal Allowed Narrowband | | |
| Interference Power: | -134 | [dBm] |
| ReDS Parameters | | |
| Peak Power (measured) | 48.0 ¹² | [dBµv/m] @3m |
| Peak Power [EIRP] | -47.2 | [dBm] |
| Distance | 200 | [meter] |
| Free Space Loss | 82.6 | [dB] |
| Frequency | 1611.00 | [MHz] |
| Wall attenuation | 15 | [dB] |
| Total Attenuation | 97.6 | [dB] |
| Equivalent Received Interference | -144.8 | |
| Power Level | | [dBm] |
| Margin From maximal allowed | | |
| narrowband interference | -10.8 | [dB] |

Sensible agrees with the limits proposed by Iridium with the following two exceptions.

First, the ReDS System should be allowed to operate with stepped frequency modulation in **approximately** 16 steps between 1005 MHz and 1709 MHz. Second, dwell time on any one frequency should not be limited to 4 milliseconds in any 85 millisecond period. However, the Commission could instead limit peak power to 48 dBµV/m at three meters over all frequency

¹¹ ICAO, *Draft Technical Specification for Aeronautical Mobile Satellite (Route) Service (AMS(R)S) Provided by Iridium Satellite System*, https://www.icao.int/safety/acp/Inactive working groups library/ACP-WG-M-Iridium-3/IRD-SWG03-WP02-Draft Iridium AMS(R)S Tech Manual 110105.pdf (last visited Mar. 26, 2018).

¹² As measured in the lab, higher frequencies have a slightly higher peak power than lower frequencies.

bands, average power as indicated in the waiver request, ¹³ and limit dwell time on any one frequency to 4.5 milliseconds.

III. Reply to NRAO's Comments

The NRAO notes that Sensible's waiver request makes no mention of the passive service band at 1400-1427 MHz but nonetheless asks the Commission to "take whatever steps it can" to prevent interference to remote sensing in the band. NRAO also suggests establishing coordination protocols for the 1610.6-1613.8 MHz and 1660-1668 MHz bands. 15

For the technical reasons articulated above, ¹⁶ radiation from ReDS devices will be well below the noise level of satellite born sensors that operate from 400 to 800 km in altitude in the 1400-1427 MHz band. Regarding NRAO's request for coordination in the two other bands, the ReDS System frequency 1611.0625 MHz falls within the 1610.6-1613.8 MHz band, while no frequency falls within the 1660-1668 MHz band.

The analysis below shows that coordination with earth radio-astronomy stations is unnecessary. The analysis assumes one kilometer of distance between a radio astronomy earth station and a ReDS device, which is reasonable given the remoteness of such earth stations and low density of ReDS devices. Because such earth stations use highly directional antennas facing the sky, it is also reasonable to assume that off-beam rejection is at least 30 dB. In addition, the analysis assumes a 30 K temperature of such an antenna facing the sky.

¹³ See Waiver Request.

¹⁴ NRAO, Comments, ET Docket No. 18-39, at 2 (filed Mar. 12, 2018).

¹⁵ See id

¹⁶ See supra Sections I, II.

Table 4: Earth Station Analysis

| K | 1.38E-23 | [W/KH] |
|------------------|----------|----------|
| T | 30 | [k] |
| В | 100 | [Hz] |
| KTB | 4.14E-20 | [W] |
| Antenna Noise | -163.83 | [dBm] |
| dBm | | |
| | | |
| Peak Power | 48.00 | [dBµv/m] |
| | | @3m |
| Peak Power | -47.20 | [dBm] |
| [EIRP] | | |
| Distance | 1000.00 | [m] |
| Frequency | 1611.00 | MHz |
| Wall Attenuation | 15.00 | [dB] |
| Free Space Loss | 96.58 | [dB] |
| Antenna Off Beam | 30.00 | [dB] |
| Total Att | 141.58 | [dB] |
| Equivalent | -188.78 | [dBm] |
| Received Power | | |
| Margin From | -24.95 | [dB] |
| Thermal | | |

This analysis shows that ReDS Systems radiation falls well below the noise level of a radio astronomy earth station. It also shows, by comparison, the resiliency of satellite born passive sensors operating in the 1400-1427 MHz band to ReDS device signals. Satellite born sensors' distance factor is at least 400 relative to a radio astronomy earth station (400 km versus 1 km, translating to 52 dB). This factor further increases when adding a sky-to-earth temperature factor (*e.g.*, of 7 dB), and then reduces by an in-beam to off-beam factor (*e.g.*, of 40 dB), which causes a further increase of the -24.95 dB margin between interference and noise. So, with the above values, the margin for satellite born sensors would be 19 dB greater than the margin for radio astronomy.

IV. Conclusion

For the reasons discussed above and in Sensible's request, the Commission should grant a limited waiver of its Part 15 rules for UWB medical imaging devices to allow the ReDS System to help manage care for patients suffering from congestive heart failure.

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March 27, 2018

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